

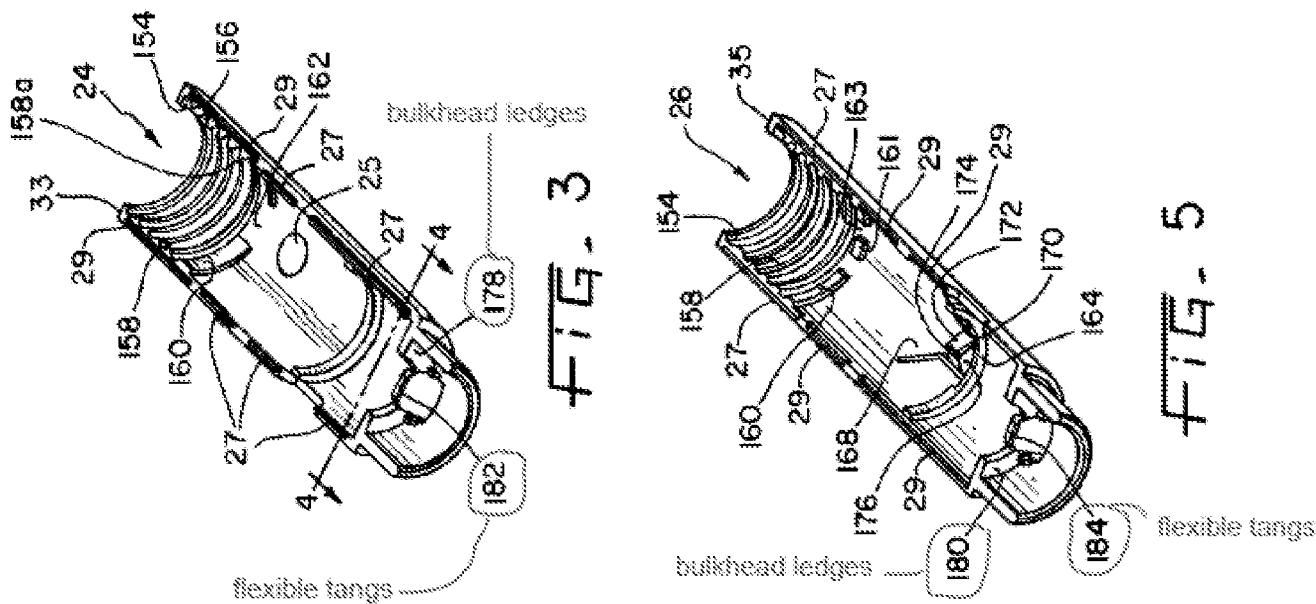
REMARKS

Claims 1 and 22 were rejected as being indefinite under 35 USC 112, second paragraph. The Examiner believed the structures of “dose setting means” and “dose expelling means” were not clearly stated in the specification or shown in the figures. This amendment deletes these claim terms in claim 1 and replaces them with the structures “dose dial sleeve” and “piston rod,” respectively. Textual support for these structures is found throughout the specification and in the drawings as items 50 and 32, respectively, and, as such, no new matter has been added. Claim 1 was also amended to add a “cylindrical insert” that is rotationally and axially fixed to the housing. Claim 22 is now cancelled. In light of the present amendment, Applicant respectfully submits the rejection under 35 USC 112 is now moot and should be withdrawn.

Claims 1-4, 7-9, 11-15, 17, 18, and 22 were rejected under 35 USC 102(b) as being anticipated by Burroughs et al. (US 6,221,046). As shown above, independent claims 1 and 2 have been amended. Specifically, claim 1 now requires a “cylindrical insert.” Applicant requests that the Examiner review the following comments, which Applicant believes clearly distinguish its invention from that taught in Burroughs et al.. Indeed, Applicant respectfully submits that reliance on Burroughs et al. fails as an anticipatory reference because ***all*** the elements recited in the presently pending claims are not found in Burroughs et al..

Claim 1 now requires a “cylindrical insert.” In rejecting claim 2, the Examiner states that Burroughs et al. teaches an “insert” and points to elements 178 and 180. However, these elements do not comprise an “insert,” but instead are “bulkhead ledges” that are part of the housing “to reduce the diameter through the proximal end of the housing.” (see Col. 9, lines 8-9 of Burroughs et al.). These bulkhead ledges, as shown

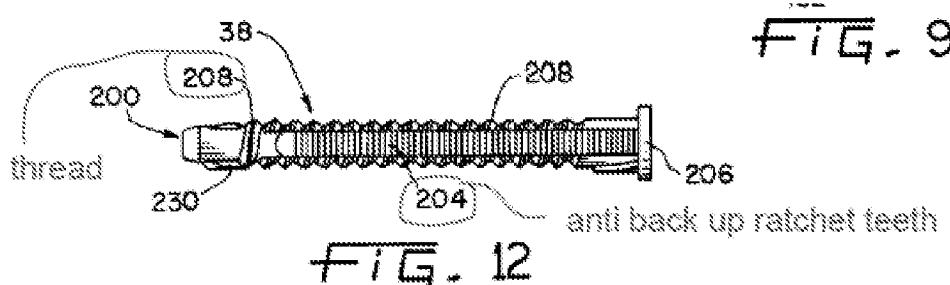
below, cannot possibly comprise the "insert" of Applicant's invention as that term is defined in the instant application.



Moreover, the Burroughs et al. bulkhead ledges are not even a single structure, but instead are two separate pieces of half circle ridges that form at best an inner wall when the two halves 24 & 26 are connected to each other. These ledges cannot be considered to be a "cylindrical insert" as presently claimed in claim 1 and they clearly do not have a "cylindrical portion that extends in a proximal direction enclosing a portion of the piston rod," likewise as required by amended claim 1.

The Examiner also alleges that the bulkhead ledges of Burroughs et al. allow the piston rod to rotate. This is completely wrong. In fact, the opposite is true; the piston rod 38 in Burroughs et al. can **never** rotate with respect to the bulkhead ledges or any other part of the housing because of flexible tangs 182 and 184 prevent the piston rod

from rotating. These tangs extend inwardly into an annulus that is created when the two half circle ledges are mated as the two parts of the housing 24 and 26 are joined together. The two tangs are locked into the anti-back up teeth 204 on the piston rod. As shown below, these anti-back up teeth run the length of the piston rod.



Indeed, the specification of Burroughs et al., as shown below, clearly states the piston rod (leadscrew 38) **cannot** rotate.

sponding rotation of nut 36. Rotation of leadserew 38 is prevented by a key-keyway type of engagement between the anti-backup tangs 182 and 184 and leadscrew 38. As shown in FIG. 1, tangs 182, 184 form a key, and leadserew 38 forms a keyway which comes into contact with the sides of the key.

(Col. 10, lines 26-28).

Movement of leadserew 38 is prevented in the proximal direction due to anti-backup tangs 182, 184 being in engagement with ratchet teeth 204. This assures that head 206 of leadserew 38 remains in constant engagement with piston 210 at all times.

(Col.11, lines 51-56).

Thus, the keys (tangs 182 & 184) are locked into keyways defined by the flat sides of the piston rod 38 containing anti-backup teeth 204. This key in the keyway is what prevents rotation of the piston rod 38. In contradistinction, the presently pending claim 2 of Applicant's application specifically requires the piston rod (i.e., leadserew) to rotate.

Thus, this claim term is not present in Burroughs et al.. In fact, Burroughs et al. teaches in the opposite direction, i.e. preventing rotation.

Claim 2 of Applicant's claims also requires an "insert" and, as described above, Burroughs et al. clearly does not have an insert. Instead, Burroughs et al. has only the two half circle bulkhead ledges. Thus, Burroughs et al. does not teach each and every element of claim 2. Additionally, claim 2 requires that the piston rod rotate in only one direction. As stated above, the piston rod 38 of the Burroughs et al. **cannot** rotate in **either** direction.

Pending claim 2 also requires a "ratchet" that is configured only to allow the piston rod to rotate in a single direction. Since the piston rod 38 of Burroughs et al. cannot rotate in any direction, it clearly cannot teach rotation only in a single direction. The Examiner further alleges that flexible tangs 182 and 184 comprise the "ratchet" claimed in claim 2. Although it is technically correct that these tangs are part of a ratchet mechanism, they **do not** function to prevent **rotation** of the piston rod. Instead, they function to prevent **axial movement** of the piston rod in the proximal direction. As stated above, the piston rod in Burroughs et al. is always prevented from rotating any in direction because of the key and keyway arrangement formed between the tangs and the flat sides of the piston rod defined by ratchet teeth 204. As such, Burroughs et al. does not disclose a "ratchet" as that term is defined in the pending application.

The Examiner is also mistaken with respect to the function of the nut 36 disclosed in Burroughs et al., which the Examiner alleges is the same as the "drive sleeve" of presently pending claim 2. Applicant's drive sleeve must be "axially displaceable but not rotatable with respect to the piston rod." As the excerpt below from

the Burroughs et al. reference clearly states, the nut 36 rotates about the thread 208 on the outside surface of piston rod (leadscrew) 38.

ring 91 and surfaces 33, 35 of housing parts 24, 26. Rotation of dial mechanism 34 causes rotation of nut 36 so that internal helical raised groove 198 of nut 36 rotates along external threads 208 of leadscrew 38 to cause nut 36 to axially retract a corresponding axial distance. Rotation of

(col. 10, lines 38-42).

In summary, as described above, the Burroughs et al. reference dose not disclose each and every element of either claim 1 or claim 2, and therefore cannot anticipate these claims. Since all the remaining claims are dependent directly or indirectly on claim 2, the Burroughs et al. reference likewise fails to anticipate those claims as well.

Applicant submits that pending claims 1-4, 7-9, 11-15, 17, and 18 define patentable subject matter and, as such, this case is now in condition for allowance. Applicant respectfully requests an early indication of same. If for any reason the application is not in condition for allowance and a telephonic conference would be helpful, please do not hesitate to contact the undersigned directly at 312/913-2143.

Respectfully submitted,

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